REMARKS

I. Status of the claims

Applicants respectfully request the rejoinder and consideration of the withdrawn claims upon the identification of allowable subject matter in generic and/or linking claims.

Claims 1, 5, 18, 44, and 45 have been amended and claim 47 has been added to the application. Claims 1, 44, and 45 have been amended to recite "particles" of an active agent, and claims 1 and 45 have additionally been amended to state that "the gel forming substance forms a matrix surrounding the nanoparticulate active agent particles and surface stabilizer." Exemplary support for these amendments can be found in the application at page 34, paragraph [00130]. In addition, claims 1, 44, and 45 have been amended to state that the composition comprises from about 20% up to about 97% water. *See e.g.*, pages 11-12, paragraph [0038]. Claim 5 has been amended to be consistent with the amendment to claim 1. Claim 18 has been amended to delete the terms "semi-crystalline" and "semi-amorphous." Finally, new claim 47 is directed to a gelatin dosage form made by a specified process. *See e.g.*, page 34, paragraph [0132].

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

II. Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-8, 12-22, 24-28 and 30-43 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. Office Action dated October 20, 2006, and page 3 of the Advisory Action dated January 24, 2007. Specifically, the Examiner asserts that:

> The amendment reciting "wherein the composition comprises at least about 5% by water, based on the total weight of composition" is new matter.

Applicants respectfully traverse the rejection.

As amended, the pending claims recite a water content of "about 20% up to about 97%." Exemplary support for this claim limitation can be found at paragraph 38 of the application, which recites:

> The gelatin dosage forms of the present invention, which retain excess water, disperse and essentially melt upon administration. The amount of water retained by the gel formulation of the invention is at least the amount required to provide for redispersability of the nanoparticulate active agent particles upon administration. This equates to a water content of from about 5% to about 97%, from about 20% to about 95%, from about 30% to about 92%, from about 45% to about 90%, or from about 65% to about 85%, based on the total weight of the composition.

As the claim language is supported by the written description of the application, withdrawal of this ground for rejection is respectfully requested.

III. Rejections Under 35 U.S.C. § 102

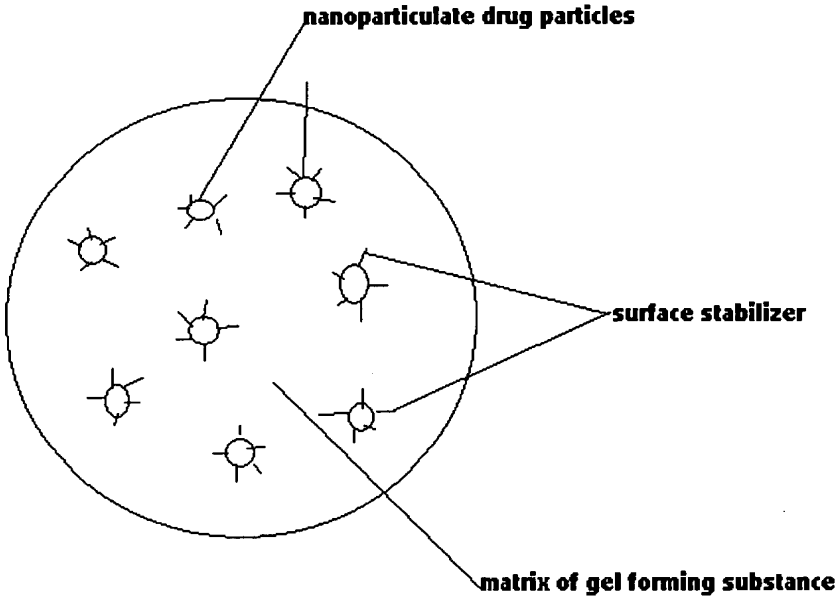
Claims 1-8, 12-22, 24-28 and 30-43 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 00/18374 to Swanson *et al.* ("Swanson"), and claims 1-8, 12-22, 24-28 and 30-33 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 6,316,029 to Jain *et al.* ("Jain"). Office Action dated October 20, 2006 at pages 3-5 and Advisory Action dated January 24, 2007 at page 3. Applicants respectfully traverse these grounds for rejection.

Swanson refers to controlled release dosage forms in which the nanoparticulate composition can be encapsulated in a hard or soft gelatin capsule. *See* page 6, lines 1-3, of Swanson. Swanson also teaches that gelatin may be used as a surface stabilizer for a nanoparticulate active agent, which is incorporated into the described controlled release dosage form. *See* page 11, line 20, of Swanson. Finally, Swanson teaches that gelatin can be used as a rate controlling polymer. *See* page 13, line 28, of Swanson.

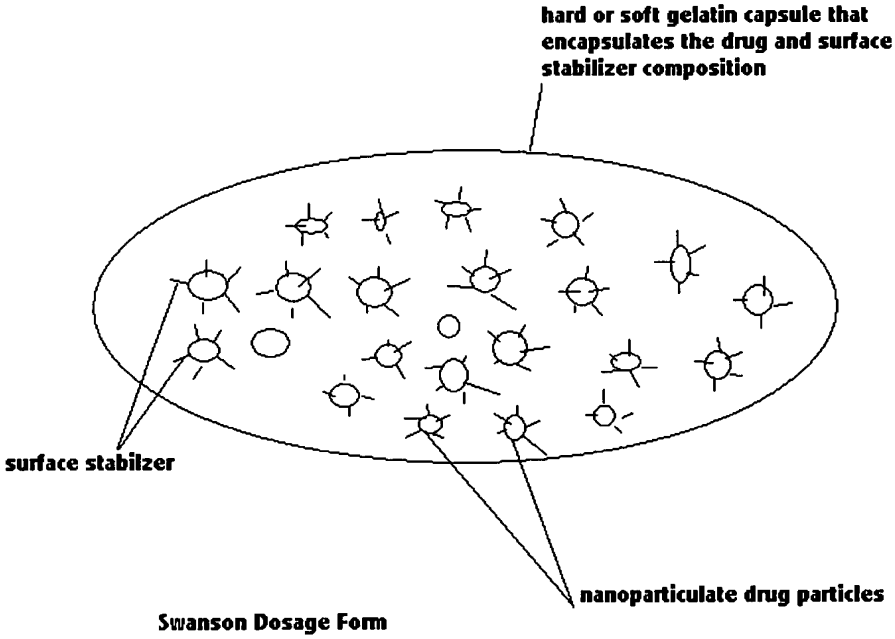
The Examiner, at page 4 of the Final Office Action, was unpersuaded by the applicants' previous arguments that the rate controlling polymer of Swanson does not anticipate the gel-forming substance of the instant claims because "the purpose of the material, as defined in the [applicants'] specification, is not a limitation that is properly incorporated in to the claims." Moreover, the Examiner alleged that Swanson's "soft gelatin capsules [sic] are understood to inherently include at least 5% water," Thus anticipating applicants' claims.

(a) The "Gelatin Capsule" of Swanson Does Not Teach or Suggest Applicants' Claimed Gel Matrix Composition

Applicants first point out that claim 1 requires the pharmaceutical composition to be a solid or semi-sloid gelatin pharmaceutical composition which forms a matrix surrounding the nanoparticulate active agent particles. As illustrated below, this feature distinguishes the claims from the gelatin capsule of Swanson. At the same time, this feature distinguishes the claims from the teaching by Swanson that gelatin can be used as a surface stabilizer or a rate controlling polymer. .



Applicants' Claimed Drug Dosage Form



Swanson Dosage Form

(b) In Contrast to the Claimed Invention, Swanson Does Not Disclose a Dosage Form Comprising about 20% up to about 97% Water

Second, because the composition is a solid or semi-solid gelatin pharmaceutical composition where the gelatin forms a matrix surrounding the nanoparticulate agents, the applicants have amended claim 1 to clarify that the resulting water content of the solid or semi-solid gelatin pahrmaceutical composition is "about 20% up to about 97%." This claimed feature is also notfairly taught or suggested by Swanson.

If, for the sake of argument, the Examiner contends that gelatin is used as a surface stabilizer or as a rate controlling polymer in the compositions of Swanson, Swanson does not fairly teach or suggest that the resultant composition will necessarily or inherently contain "about 20% water up to about 97%" water. As noted in Applicants response dated January 8, 2007, Examples 1-17 of Swanson describe the use of water in the process of making various compositions; however, this water is subsequently removed from the composition in a drying step. Nonetheless, the Examiner responded in the Advisory Action that because gelatin is hygroscopic and it could be present in the resultanting soft gelatin dosage form of Swanson, it inherently anticipates the applicants' claim to a composition having a water content of 5% or greater.

The equilibrium moisture content of dry gelatin at 20°C and 50% relative humidity (*i.e.*, general room temperature and storage conditions) is about 10-12% water content. *See* Figure 1 of Exhibit 1 ("Gelatin" in *Handbook of Pharmaceutical Excipients* (Rowe et al.), pp. 252-254, (2002)). This means that if a dry dosage form, such as that described by Swanson, includes gelatin in its composition and the composition is exposed to general room conditions, at most the gelatin in the dosage form will absorb 10-12% water. Thus, the dosage forms of Swanson do not teach or suggest the claimed compositions comprising "about 20% up to about 97% water." Accordingly, withdrawal of this ground for rejection is respectfully requested.

(c) In Contrast to the Claimed Invention, Jain Does Not Disclose a Dosage Form Comprising about 20% up to About 97% Water

The rejection in view of Jain was asserted under 35 U.S.C. § 102(b), while the prior rejection in view of Jain was asserted under 35 U.S.C. § 102(a). In light of the priority date of the present application of September 11, 2002, Applicants believe that the Examiner intended to assert the rejection under 35 U.S.C. § 102(a). Applicants respectfully traverse the rejection as it may have been applied to the pending claims.

Jain is directed to fast melt dosage forms comprising a nanoparticulate active agent. The compositions comprise a solid dose matrix comprising at least one pharmaceutically acceptable water-soluble or water-dispersible excipient, wherein the solid dose matrix disintegrates or dissolves upon contact with saliva in less than about 3 minutes. Jain teaches that one exemplary pharmaceutically acceptable water-soluble or water-dispersible excipient is gelatin. Jain also teaches that gelatin may be used as a surface stabilizer for a nanoparticulate active agent, which is incorporated into the described fast melt dosage form. In the Examples of the patent, an aqueous dispersion of a nanoparticulate active agent is spray-dried to form a granulate, followed by tabletting of the granulate.

In the Advisory Action, the Examiner asserted that Jain discloses processes in which the components are blended with water at amounts greater than 5%, and because gelatin is hygroscopic, the resultant compositions would be expected to have a water content of 5% or greater. Applicants respectfully disagree with the Examiner's analysis of Example 3 of Jain.

The Examiner cited to Example 3 of Jain. Example 3 provides that "approximately 20 g of deionized water was passed through the feed tubing and sprayed on the granules." The process of making the dosage from does not end with this step. In fact, the water sprayed on the granules is removed: "At the end of the spraying process the granules were dried by fluidizing for 5-7 minutes." Accordingly, Example 3 of Jain does not fairly teach or suggest that the resulting granules have any water content, let alone greater than the now claimed "about 20% up to about 97% water."

Moreover, as noted above, even if the resulting dry granules of Jain contain gelatin as an excipient or as a surface stabilizer, the resulting equilibrium moisture content of dry gelatin at 20°C and 50% relative humidity is about 10-12% water content. *See* Exhibit 1. This means

that if a dry dosage form, such as that described by Jain, is exposed to general room conditions, at most the dosage form will absorb 10-12% water. Thus, the dosage forms of Jain do not teach or suggest the claimed compositions comprising "about 20% up to about 97% water." For at least these reasons, withdrawal of this ground for rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully believe that all rejections have been rendered moot, accommodated, or overcome. Applicants respectfully request that the Examiner reconsider and withdraw the present rejections, and allow the pending claims. As Applicants believe that the pending claims are in condition for allowance, Applicants also request that the Examiner rejoin and examine the withdrawn claims.

If it is believed that telephone communication can expedite the prosecution of this application, the Examiner is invited to contact the undersigned at the number below.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date 17 August 2007

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